MAR 2 9 2006

K060344

# 510(k) Summary
# O-arm™ Imaging System with 1-D Display Control Mouse (January 2005)

## Submittal information:

Chas Burr
Breakaway Imaging, LLC
300 Foster Street
Littleton, MA 01460

Phone: 978-952-2646

## Device name and classification

| | |
|---|---|
| Proprietary Name: | O-arm™ Imaging System |
| Classification Names: | Mobile X-ray System, Solid-state X-ray Imager |
| Classification Panel: | Radiology |
| CFR Sections: | 21 CFR 892.1720, 21 CFR 892.1650 |
| Class: | II |
| Product Codes: | IZL, MQB |

## Substantial Equivalence

The O-arm™ Imaging System with the 1-D Display Control Mouse is substantially equivalent to the O-arm™ Imaging System, which was cleared in 510(k) K050996.

The display control functions provided by the optional sterile disposable wireless 1-D Control Mouse are also provided by console controls and by a non-sterile, hard-wired mouse on the standard O-arm™ Imaging System.

## Device Description

The O-arm™ Imaging System is a mobile x-ray system which provides 3D imaging as well as 2D fluoroscopic imaging.

The system consists of two parts: the x-ray O-arm™ Stand (comprising x-ray generator, flat dynamic x-ray detector, and the x-ray control user interface) and the mobile view station (comprising the image processors, a user interface for image and patient handling, and viewing monitors).

The 1-D Display Control Mouse is an optional accessory. It is a sterile disposable limited-function wireless mouse. With the 1-D Mouse, a surgeon can remotely

control and point at the O-arm™ image display. The 1-D mouse is similar to remote controls for controlling projectors during business presentations. The 1-D Mouse allows the surgeon to control what is displayed and to point out features on the image with a laser pointer. The sterile and wireless characteristics allow use by the surgeon without compromising the sterile field and without cluttering the surgical area with a mouse cable. No clinical information is transmitted by mouse, only display control commands.

## Intended Use

The O-arm™ Imaging System is designed for 2D Fluoroscopic and 3D imaging for intraoperative applications in surgical theaters, particularly for orthopedic applications. The O-arm™ Imaging System is compatible with certain Image Guided Surgery Systems.

## Comparison with the Predicate Device

| | **O-arm™ Imaging System with 1-D Mouse** | **O-arm™ Imaging System** |
|---|---|---|
| **Physical configuration** | A portable system with separate viewing station. The imaging unit is full circle or "O-arm". | |
| **Imaging modes** | 3-D imaging and 2-D fluoroscopy | |
| **Intended use** | Intraoperative imaging | |
| **Image display control** | **Includes an optional sterile, single-use, wireless, 1-D mouse** in addition to the standard reusable, hardwired PC mouse | Standard reusable, hardwired PC mouse |

## Similarities and Differences

The O-arm™ Imaging System with 1-D Mouse is virtually identical in safety and effectiveness to the previously cleared O-arm™ Imaging System. The only difference is that the hardwired PC mouse, which is used to control the display image, may be replaced by an optional sterile, single-use, wireless, 1-D mouse. The 1-D mouse provides simpler controls, reduced cable clutter, and greater assurance of maintaining the sterile field. The low power, unique communication protocol, and limited function of the 1-D Mouse ensure no co-existence, data latency and integrity, or security issues that might affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Mr. Rick Grant
President and CEO
Breakaway Imaging, LLC
300 Foster Street
LITTLETON MA 01460

Re: K060344
Trade/Device Name: O-arm™ Imaging System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: February 9, 2006
Received: February 15, 2006

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): __N/A K060344

Device Name: ___ O-arm™ Imaging System____

Indications for Use:

The O-arm™ Imaging System is designed for 2D fluoroscopic and 3D imaging for intraoperative applications in surgical theaters, particularly for orthopedic applications. The O-arm™ Imaging System is compatible with certain Image Guided Surgical Systems.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060344